Certified Minority Owned Small Business

OQSIE

QMS GAP ASSESSMENT

Providing your team with actionable insights to streamline activities and improve operations and performance.

Irvine, California

www.oqsie.com

What We Do

We leverage advanced analytics to help Quality leaders identify compliance risks and areas of opportunity for improvement.

- Strong framework and advanced tools
- High value, low cost
- Highly experienced industry professionals

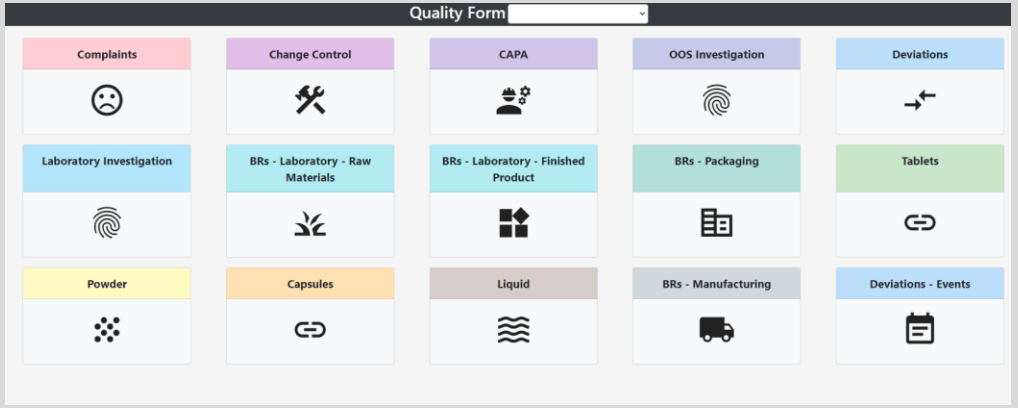
High Level Review & Assessment	Deep Dive Review & Assessment
2 to 6 weeks	1 to 3 months
1 to 4 consultants	2 to 20 consultants
~$15k per QS element	~$50k per QS element

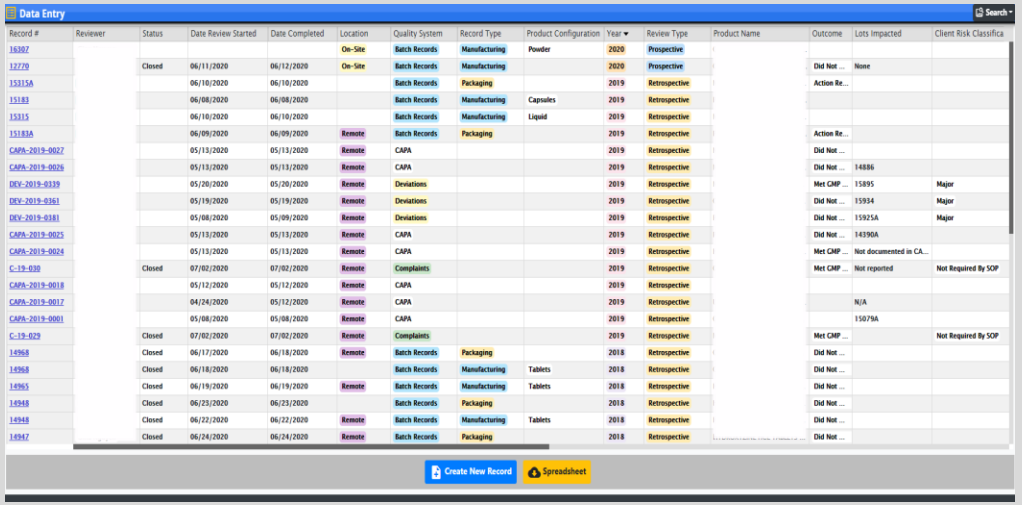
We conduct analyses for each Quality System (QS) element, we look at multiple regulatory and operational dimensions, well beyond the review of your SOPs vs cGMPs.

- **Quality System Elements:** Batch Records, Deviations, CAPA, Complaints, Change Control, etc.
- **Dimensions:** QA Oversight, RCA, Risk Assessment, Effectiveness Check, cGMP, SOP adherence, GDP, etc.

How We Do It

1. Deploy proprietary templates and checklists
2. Highly experienced consultants review Quality System element documents
3. Apply advanced analytics to generate insights on outcome of reviews





Case Study

Situation:

A pharmaceutical company received a Warning Letter, OQSIE performed a gap assessment on the Quality System elements cited on the Warning Letter and developed a comprehensive remediation plan.

Approach:

Team of 20 consultants performed a deep dive assessment of all quality system elements leveraging our proprietary templates and checklists.

Outcome:

OQSIE identified and prioritized the areas of regulatory risk and opportunity for improvement for each QS element, and created a comprehensive remediation plan with the following major initiatives:

- SOP redesign for Quality System elements identified in the Warning Letter
- Remediation of Quality Systems not cited in the Warning Letter
- Interim Controls
  - Additional controls on QS currently in-scope (prospective reviews)
  - Controls on QS not currently in-scope (prospective reviews)
- Other pro-active initiatives
  - ANDA vs MBR Remediation
  - Batch Record harmonization and simplification
  - Reconfiguration of MasterControl

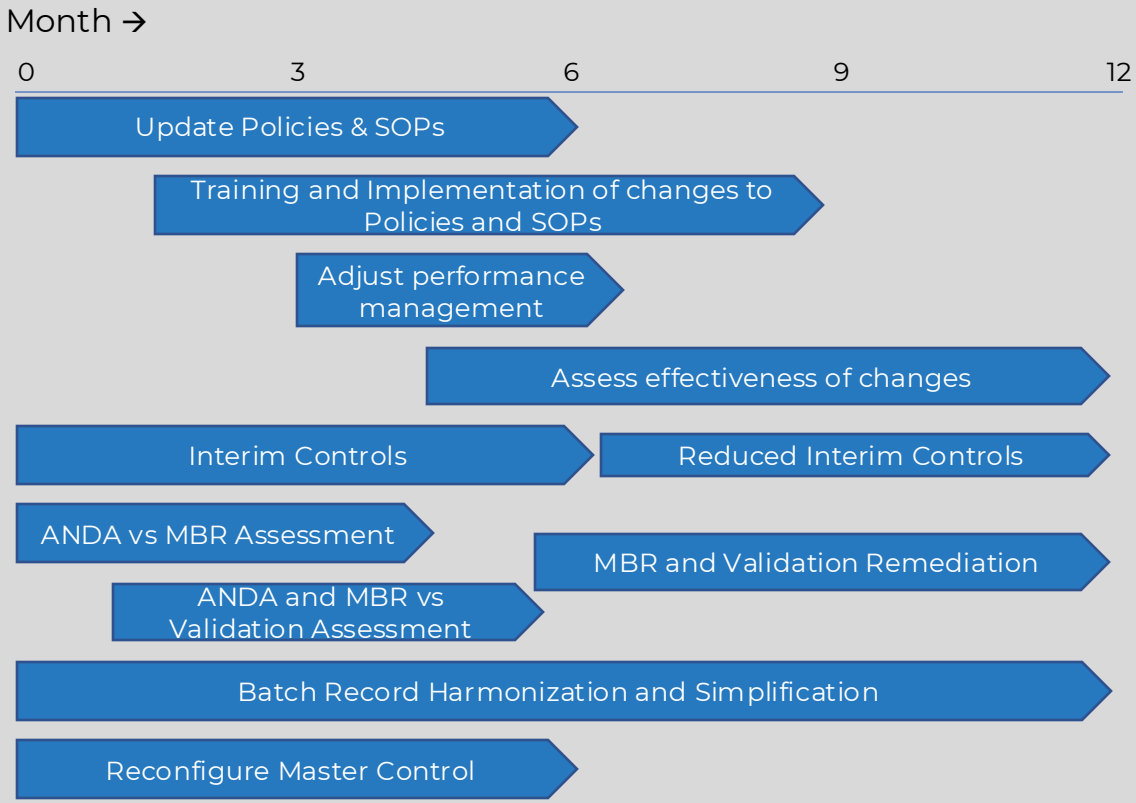
Case Study

Example of content of the Gap Assessment:

Summary of Findings

Quality Systems Assessed	Synthesis of assessments
Complaints	High risk of additional regulatory action
Change Control	High risk of additional regulatory action
CAPA	High risk of additional regulatory action
Deviation Management	High risk of additional regulatory action
Validation	High risk of additional regulatory action
Laboratory Controls	Risk of additional regulatory action
Batch Release	Needs significant improvement
Training	Needs a different structure and approach

High Level Timeline of Remediation Plan



Case Study

Examples of Gap Assessment reports:

Key Activities

1. **Define Strategy for Policies & SOPs**
   - Develop proposed strategy for Policies and SOPs
   - Syndicate proposed strategy with management team
   - Develop detailed plan to update relevant documents
2. **Update Policy & SOP documents**
   - Update policy documents
   - Update SOP documents
   - Implement governance process to accelerate approval process
   - Define KPI(s) for effectiveness check
3. **Process Change Control and Develop Training Materials**
   - Change Control submission
   - In parallel, develop training materials for new and updated documents
   - Develop training plan
   - Define implementation plan and execute
4. **Training and Implementation**
   - Deliver training
   - Execute implementation plan
5. **Assess Change Effectiveness**
   - Conduct effectiveness check(s)
   - If necessary, develop additional remediation plan

Common Areas impacting Quality Systems ↓	Complaints §211.198	Investigations §211.192	QC Records §211.194	BR Reviews §211.188	Change Controls §211.100	CAPAs §211.192	QC Lab Inv. §211.194
GMP Compliance	Deficient	Deficient	Deficient	Deficient	Deficient	Deficient	Deficient
Process / SOP	Deficient	Deficient	Deficient	Deficient	Deficient	Deficient	Deficient
Training	Insufficient	Insufficient	Insufficient	Insufficient	Good	Good	Insufficient
Performance (SOP not followed)	Insufficient	Insufficient [2]	Good	Good	Good	Good	Insufficient
Deviations	Good	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient	Good
Investigations (RCA and RA) [1]	Insufficient	Insufficient	Insufficient	Insufficient	Good	Good	Insufficient
CAPA	Good	Insufficient	Good	Good	Good	Good	Insufficient
Systemic Challenges	Deficient	Deficient	Deficient	Deficient	Deficient	Deficient	Deficient
GDP	Good	Insufficient	Insufficient	Insufficient	Good	Insufficient	Good
Equipment	Good	Good	Insufficient	Good	Good	Good	Good
Data Integrity	Good	Good	Insufficient	Insufficient	Good	Good	Good
EQMS [3]	Good	Good	Good	Good	Good	Insufficient	Good
Records	Deficient	Deficient	Deficient	Deficient	Deficient	Deficient	Deficient
Validation	Good	Good	Insufficient	Insufficient	Insufficient	Insufficient	Insufficient
Adverse Event Complaints	Insufficient Third Party Contractor	Good	Good	Good	Good	Good	Good

Process	Assessment	Warning Letter?	SOP In Place	SOP in Compliance
Written procedures describing the handling of all written and oral complaints.	Does not meet criteria		Yes	No
QA Unit review of drug products that failed to meet specifications.	Complies			
For drug products that potentially failed to meet specifications, an investigation is conducted.	Does not meet criteria			
Process to identify serious and unexpected adverse drug experience (ADE).	Does not meet criteria			
Process to report the food and drug administration any ADE.	Does not meet criteria			
Written records for each complaint.	Does not meet criteria			
Files of each written complaint must be readily available for inspection.				
Written records must be maintained for specific time, per expiration date or complaint date, whichever is longer.				
Written records include (where known), Name and strength of the drug product. Lot number, name of complainant, and reply to complainant.				
Investigations include the findings and follow up.	Does not meet criteria			
Written record of investigations related to complaints are readily available.				
If an investigation is not conducted, a documented reason as to why the investigation was not conducted and the name of the person making such determination.	Does not meet criteria			

We deliver detailed reports for each Quality System element.

Common Areas impacting Quality Systems ↓	Complaints	Investigations	QC Records	BR Reviews	Change Controls	CAPAs	QC Lab Inv.
GMP Compliance	Deficient	Deficient	Deficient	Deficient	Deficient	Deficient	Deficient
Records	Deficient	Deficient	Deficient	Deficient	Deficient	Deficient	Deficient
Process / SOP	Deficient	Deficient	Deficient	Deficient	Deficient	Deficient	Deficient
Investigations (RCA and RA) [1]	Insufficient	Insufficient	Insufficient	Insufficient	Good	Good	Insufficient
Systemic Challenges	Deficient	Deficient	Deficient	Deficient	Deficient	Deficient	Deficient

Work With Us

We offer the **best value** for our client's money in the industry.

CONTACT:

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